ORION-4

Cardiovascular Outcomes Trial (NCT03705234)

ONGOING

Phase 3 Study

ORION-4 is a Phase 3, double-blind, randomized, placebo-controlled study to evaluate the effect of inclisiran treatment on the incidence of major adverse cardiovascular events (referred to as “MACE”) in high-risk atherosclerotic cardiovascular disease (ASCVD) patients. The primary endpoint is a composite of coronary heart disease death, myocardial infarction, fatal or non-fatal ischemic stroke and urgent coronary revascularization procedures. The secondary endpoints include a composite of coronary heart disease death or myocardial infarction, and cardiovascular death.

The study is being conducted together with Oxford University in the United Kingdom and the TIMI Study Group in the United States.

PATIENT POPULATION

15,000 participants 55 years or older with pre-existing ASCVD (determined by prior history or evidence of myocardial infarction, ischemic stroke, peripheral artery disease as evident by prior lower extremity artery revascularization, or aortic aneurysm repair) and not at their LDL-C goal.

LOCATIONS

150 sites in the United Kingdom and United States

STUDY TIMEFRAME

October 2018 – 2024*

METHODOLOGY

Trial participants will receive inclisiran sodium 300 mg or matching placebo given by subcutaneous injection on day one, again at day 90 (three months) and then every six months thereafter in a 1:1 ratio for a planned median duration of five years, with a planned interim analysis for efficacy occurring at a median follow-up of four years.

** Estimated primary completion date.*

Inclisiran is an investigational drug not yet approved for use by the FDA or any other regulatory authority.

Updated August 2019.